

UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

AR BUTUS BIOPHARMA CORPORATION : Case No. 1:22-cv-00252-MSG  
et al. :  
Plaintiffs, :  
v. : Philadelphia, Pa.  
: March 16, 2023  
MODERNA, INC. et al. : 10:01 a.m.  
: Defendants. :  
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TRANSCRIPT OF TELEPHONIC CONFERENCE HEARING  
BEFORE THE HONORABLE MITCHELL S. GOLDBERG  
UNITED STATES DISTRICT COURT JUDGE

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1 (Call to Order of the Court)

2 THE COURT: Good morning. It's Mitch Goldberg. I  
3 would appreciate -- we're just going to talk about scheduling  
4 and would appreciate just one Lawyer per side, Plaintiff and  
5 Defendant, speaking.

6 Let me first confirm that we're on the record.

7 Jimmy, are you on the call?

8 THE DEPUTY CLERK: Yes, Judge. Good morning.

9 THE COURT: And we're on the record?

10 THE DEPUTY CLERK: Yes, Judge.

11 THE COURT: Okay. All right. So, I'm happy to hear  
12 -- identify the Lawyers on the call. So why don't we start  
13 with the Plaintiffs?

14 KAREN KELLER: Good morning, Your Honor.

15 Karen Keller from Shaw Keller. With me today is Nate Hoeschen  
16 from my office.

17 I have David Berl and Adam Harber on behalf of  
18 Roivant and Genevant. They're on the line from  
19 Williams & Connolly. And David Berl will be handling the  
20 discussion. Also on the line is Kira Davis and Nate Tan from  
21 Morrison & Foerster on behalf of Arbutus.

22 THE COURT: All right, good morning. And for  
23 Moderna?

24 BRIAN EGAN: Good morning, Your Honor. This is  
25 Brian Egan from Morris, Nichols on behalf of Moderna. Joining

1 me today from Kirkland & Ellison are Pat Carson and  
2 Mark McLennan. And Ms. Carson will be handling our side.

3 THE COURT: Okay. Injure United States have a  
4 couple basic questions I wanted to get clarified. And I don't  
5 think the scheduling is that far off.

6 So, what I'll do after my questions is just open it  
7 up to discussion as to any point on scheduling anyone wants to  
8 make. I don't have any specific questions about scheduling.

9 But I want to first understand a couple things  
10 better. And I'm asking first this question of  
11 Plaintiffs' Counsel.

12 Is it -- could someone explain to me in more detail  
13 than what's set out in the Complaint the relationship between  
14 Arbutus and Genevant? And are the Lawyers -- should I view  
15 those two Entities as separate Plaintiffs?

16 I mean, my sense is it's really they're saying --  
17 they're litigating the same thing. But I want to understand  
18 the relationship between those companies better. And then, the  
19 relationship between Counsel -

20 DAVID BERL: Yes.

21 THE COURT: - representing them. So, go ahead.

22 MR. BERL: Yes, Your Honor. This is David Berl from  
23 Williams & Connolly. Arbutus is the Licensee -- or sorry, the  
24 Assignee of the asserted Patents. And Genevant, my Client, is  
25 the exclusive Licensee of the Patents.

1           I think for Your Honor's purposes, the Parties are  
2 aligned. This is not as if two not-aligned Parties are  
3 advancing separate arguments in a litigation.

4           I think for Your Honor's purposes, in terms of  
5 administering the case, you can think of it as one Plaintiff.  
6 But there are two Parties, just because -

7           THE COURT: Well -

8           MR. BERL: - of the -- in terms of the size and  
9 License, and the Patent.

10          THE COURT: Okay. And the next question for -- I  
11 guess for Plaintiffs' Counsel also is I have the six Patents in  
12 suit in front of me.

13          Could you tell me which? Do you have a decision from  
14 -- I know some were challenged in the PTAB. And could you tell  
15 me which of the -

16          MR. BERL: Yes.

17          THE COURT: - six do you have a decision on? And  
18 also clarify for me whether there was Federal Circuit  
19 litigation and what the outcome of the appeal was, please?

20          MR. BERL: Yes. Yes, Your Honor. So there were two  
21 of the Patents that are asserted in the case were challenged by  
22 Moderna in the inter partes review proceedings. And those two  
23 Patents are the 069 Patent and the 435 Patent.

24          As to the 069 Patent, all of the challenged Claims  
25 were upheld by the Patent Office. So all of Moderna's

1 challenges were rejected.

2 That Decision was appealed by Moderna. And in the  
3 Decision on December 1st of 2021, the Federal Circuit affirmed  
4 on the merits the PTAB's Decision in all respect, so that  
5 there's a final Decision of the PTAB that the Patents are not  
6 invalid, and fully affirmed by the Federal Circuit. And all of  
7 that is over. The time for seeking certiorari is gone. And  
8 so, that case is completed.

9 The other Patent that Moderna challenged is the  
10 435 Patent. Some of the challenged Claims were found to be  
11 invalid. Some of the challenged Claims were found to be valid.

12 That Decision was appealed to the Federal Circuit.  
13 And the Federal Circuit on a separate Decision on the same  
14 date, also December 1st of 2021, dismissed Moderna's appeal for  
15 lack of subject matter jurisdiction, lack of case or  
16 controversy under Article 3, thereby keeping in place the final  
17 written Decision of the Patent Office Appeal Board that those  
18 claims that it had upheld were, indeed, not invalid.

19 And so, those are the set of Claims from the  
20 435 Patent that all right asserted in this case. And those  
21 have been finally adjudicated to be valid by the PTAB in the  
22 Decision that was not disturbed on appeal to the  
23 Federal Circuit. The Patents -

24 THE COURT: I heard you say on the 435 Patent, the  
25 PTAB did find certain Claims to be invalid. Is that accurate?

1                   MR. BERL: That's accurate; and that Finding was  
2 affirmed on appeal, as well. And so, those Claims are canceled  
3 and are not asserted in the case before Your Honor.

4                   THE COURT: Okay. I thought I heard you say the  
5 appeal was dismissed for lack -- maybe you said lack of  
6 standing.

7                   So how is there an adjudication on -- I'm just  
8 talking about the 435 and Finding of the PTAB that some were  
9 invalid. If there's no standing, how does the Federal Circuit  
10 get to a substantive Ruling on invalidity?

11                  MR. BERL: So the substantive Ruling on invalidity  
12 was not addressed in the 435 case. But under the relevant  
13 Estoppel Statute -- that's 35 U.S.C. § 315(e) -- the principal  
14 is that where there's a final written Decision of the  
15 Patent Office holding that the Claims had not been proven  
16 invalid, that triggers the estoppel, irrespective of whether  
17 the Federal Circuit dismisses the appeal, affirms on the merits  
18 on the appeal, or whether the Determination by the  
19 Patent Office is not appealed at all, as sometimes occurs. As  
20 long as there's a final written Decision of the Patent Office  
21 that's not disturbed, that triggers the estoppel provisions of  
22 § 315 of the Patent Act.

23                  THE COURT: Thanks; according to Plaintiffs -- and  
24 I'm going to see if Moderna has a different view on all this in  
25 a second, of courses. But, according to Plaintiffs, then,

1 what, if any, invalidity issues are in play in the case before  
2 me, and on what Patents?

3 MR. BERL: Yes; so, with respect to the 069 and  
4 435 Patents, in our view it's clear that, under the estoppel  
5 provision, Moderna is not permitted to advance any argument it  
6 made before the Patent Office or could have made before the  
7 Patent Office.

8 And so, any prior art defense, we think, is out,  
9 unless Moderna can meet the very high standard, which is rarely  
10 met, that it somehow would not have been able to advance that  
11 argument, for example, if there was no way it could have found  
12 the prior art, or something like that.

13 But, subject to it making such a showing, we think  
14 all of those prior art defenses are out for the 435 and 069.  
15 Moderna does have available to it defenses under § 112. It's  
16 not estopped from advancing those, nor is it estopped from  
17 advancing obviously arguments as to noninfringement.

18 I think the issues as to the other Patents that were  
19 not the subject of the IPR is a little more nuanced and subtle,  
20 perhaps. I think the Federal Circuit made Determinations --  
21 factual Determinations about the inadequacy of Moderna's  
22 arguments on anticipation and obviousness relating to how it  
23 was reading the prior art.

24 And in our view, background common law principles of  
25 estoppel will foreclose Moderna from making certain arguments,

1 even as to the other Patents, because it failed before the  
2 Patent Office and then before the Federal Circuit in the  
3 069 IPRs.

4 So, that, I think, is a more granular inquiry that  
5 will depend on the particular arguments that Moderna is making  
6 and whether they're estopped collaterally from advancing those  
7 arguments.

8 But, under the Statute of § 315 and the traditional  
9 statutory estoppel, that applies simply to the 069 and  
10 435 Patents. Does that -

11 THE COURT: Okay.

12 MR. BERL: - answer Your Honor's questions?

13 THE COURT: Yeah, it does. Thank you. So whoever's  
14 going to speak for Moderna -- I forgot who -- do you -- you can  
15 respond to all that. In particular, do you at least concede  
16 that the 069 and the 435 Patents are not subject to invalidity  
17 litigation based on what happened in the PTAB and the  
18 Federal Circuit?

19 PATRICIA CARSON: Your Honor, this is Pat Carson on  
20 behalf of Moderna.

21 THE COURT: Pat, could you speak up? Pat, speak up  
22 a little bit. I'm having trouble hearing you.

23 MS. CARSON: Yes, I'm sorry. Can you hear me?

24 THE COURT: Yeah, that's better. Thanks; go ahead.

25 MS. CARSON: Okay. So, for the most part,

1 procedurally what Mr. Berl was saying we don't disagree with,  
2 on the 069 and the 435.

3 I will point out that we can raise obviousness-type  
4 double patenting arguments, as a basis for invalidity. And we  
5 can also raise § 112 defenses as a basis for invalidity.

6 I think the other thing that was missing from what  
7 Mr. Berl was saying is that there is another family of Patents  
8 that are being asserted against Moderna by the Plaintiffs. And  
9 that's 2002 family. And those Patents were never challenged,  
10 so there is no estoppel there.

11 There's also a number of Patents from the family that  
12 Mr. Berl was speaking about that were not challenged, that were  
13 not estopped on prior art. As a matter of fact, one of the  
14 Patents hadn't even issued at the time of the IPR. So -

15 THE COURT: Well, I'm sorry to interrupt. You're  
16 talking about family of Patents and I'm thinking of it just as  
17 six that are in the Complaint. Are we talking about the same  
18 thing?

19 MS. CARSON: Yes, I'm sorry, Your Honor.

20 THE COURT: Okay.

21 MS. CARSON: The six Patents are from two separate  
22 families. And the -

23 THE COURT: Got it.

24 MS. CARSON: - family -

25 THE COURT: Okay.

1 MS. CARSON: - that was involved in the  
2 IPR proceedings, we will call it the 2008 family based on  
3 filing date. And that family was the family that had two  
4 Patents, two of the five Patents that are in that family -

5 THE COURT: Okay.

6 MS. CARSON: - that are in this case were assert -

7 THE COURT: Okay.

8 MS. CARSON: Were involved in the IPRs.

9 THE COURT: So what is Moderna's view on invalidity  
10 litigation regarding 069 and 435?

11 MS. CARSON: Our position is that, for the most  
12 part, what Mr. Berl was saying is correct on the Claims that  
13 were adjudicated during the PTAB proceedings. But because -

14 THE COURT: Correct that invalidity isn't in play,  
15 or correct he recited the procedural history? I'm just trying  
16 to figure out what litigation is in front of me. So let me ask  
17 it -

18 MS. CARSON: Okay.

19 THE COURT: - a different way.

20 MS. CARSON: I'm sorry, Your Honor.

21 THE COURT: Do you agree that there cannot be, based  
22 on what happened in the PTAB and the Federal Circuit, that  
23 there is a preclusive effect for you to -- which precludes you  
24 from arguing that the 069 and the 435 are invalid, agree or  
25 disagree?

1 MS. CARSON: I disagree.

2 THE COURT: Okay.

3 MS. CARSON: Because -

4 THE COURT: Explain, please.

5 MS. CARSON: - A, to the extent, as Mr. Berl said,  
6 if we can meet the high standard of something that we could not  
7 have found during the IPR, we can -

8 THE COURT: Um-hmm.

9 MS. CARSON: - raise that as prior art.

10 THE COURT: Okay. Are you going to -- are you going  
11 to pursue that high standard and that avenue?

12 MS. CARSON: At this point, I can't say that we are  
13 definitely not. What I can say that we're definitely going to  
14 pursue is a defense of obviousness-type double patenting, which  
15 is a special form of prior art -

16 THE COURT: Yeah.

17 MS. CARSON: - assertion -

18 THE COURT: Okay.

19 MS. CARSON: - that relies on other Patents that the  
20 Plaintiffs have. So we're definitely -

21 THE COURT: Um-hmm.

22 MS. CARSON: - going to pursue that basis for  
23 invalidity. And we're definitely -

24 THE COURT: Okay.

25 MS. CARSON: - going to pursue § 112 defenses of

1 invalidity against the 069 and the 435.

2 THE COURT: Okay; understood. And could you explain  
3 please your defense to infringement, generally, because, as I  
4 understand the allegations, it's that Moderna, as part of its  
5 vaccine -- and then these are the allegations -- needed a  
6 delivery platform and used the Plaintiffs' delivery platform.

7 So how do you defend? Just generally explain to me  
8 your defense on infringement in that context, please.

9 MS. CARSON: Our defense to infringement is that the  
10 Claims that the Plaintiffs are asserting recite specific  
11 limitations, particularly the amounts of the components that  
12 are present in the delivery platform. And we will have -- we  
13 are disputing that our vaccine meets those limitations.

14 And just I'd wish to point out, Your Honor, that  
15 their allegation is that we used their delivery platform. And  
16 in fact, as we said in our Answer, we used our own  
17 proprietary -

18 THE COURT: Okay.

19 MS. CARSON: - platform.

20 THE COURT: Yeah, that's -

21 MS. CARSON: And that's going to be the -

22 THE COURT: Yeah.

23 MS. CARSON: - basis for our -

24 THE COURT: That's why I emphasized alleged. So the  
25 simple answer, which it suffices for now just to help with my

1 understanding of the case, is you didn't use their delivery  
2 platform. You developed your own?

3 MS. CARSON: Yes, that's right.

4 THE COURT: Right? Okay.

5 MS. CARSON: Correct, yes.

6 THE COURT: Understood, okay. There's someone who's  
7 speaking. I'm not sure whether you wanted someone to chime in,  
8 or you think you're on mute and you're not.

9 But in any event -- okay. So the only comment I  
10 would have about scheduling, and then I'll go back to  
11 Plaintiffs' Counsel and you can tell me what you think is  
12 important and what you dispute.

13 So for cases that I handle in the EDPA, non-Patent  
14 cases, I typically have a referral to a Magistrate Judge who's  
15 available for mediation. But I'm not going to do that in this  
16 case for a lot of reasons, I think, we'd need to develop.

17 And I would just suggest if the Lawyers want to avail  
18 themselves to a Judicial Officer for mediation, obviously it  
19 can't be me. You could just -- if there's some type of  
20 agreement in that regard, just bring that to my attention and  
21 then we can brainstorm. Would it be a Federal Magistrate in  
22 EDPA?

23 We have one with -- he's doing some Delaware work  
24 with some -- so has some Patent experience, Judge Lloret and/or  
25 we could brainstorm. Would there be someone in the Delaware

1 Court available, again, Judicial Officer?

2 So I'm not going to include a Magistrate in the  
3 Scheduling Order, nor, subject to suggestion by the Parties, am  
4 I going to include -- sometimes I do this in EDPA cases --  
5 discovery referrals to the Federal Magistrate, discovery  
6 disputes. I think in a case like this, it's important for  
7 continuity and my understanding of the case that I maintain  
8 oversight over all issues.

9 So I don't think it's so important. The only other  
10 thing I would add about scheduling is I really don't think it's  
11 so important we settle on a trial date right now.

12 So I don't know that I'm going to include that in the  
13 Order. I may. But that's always subject to change. We're at  
14 the very early stages of a case.

15 So, those are my thoughts. And let's start with  
16 Plaintiffs. Is there anything you want to tell me about  
17 scheduling that you think I should take notice of?

18 MR. BERL: Sure; very briefly, Your Honor.

19 Obviously as the Plaintiffs, we would like our day in court as  
20 quickly as practicable. Obviously that's subject to your  
21 availability and schedule.

22 I think the principal objection Moderna had in its  
23 papers was that it didn't want back-to-back trials, because it  
24 has a trial scheduled. I believe it's November 12th of 2024.  
25 And it noted that it may have a case that Moderna brought

1 against Pfizer potentially scheduled in October 2024.

2 I would just observe that, in principle, it doesn't  
3 appear that Moderna is opposed to having trials on  
4 back-to-back months in October and November of 2024. It just  
5 wants its own later-filed case against Pfizer to be going first  
6 before us.

7 And well, we filed our case first. And we'd see no  
8 reason that the trial can't proceed, if not in August as we  
9 proposed, potentially in October.

10 I mean, Moderna's a big company. They have two  
11 separate set of Lawyers defending them in these two cases.

12 THE COURT: Yeah, well, we could work that out. As  
13 you know, things change. I mean, that's a long time from now.  
14 And things change a lot. So I don't want to make a Decision on  
15 my schedule, their schedule, your schedule right now so far in  
16 advance.

17 But we will pick one date if this case goes to trial.  
18 And everyone will be attached. And all Experts will be  
19 required to appear.

20 I recognize some names on the Lawyers' list of  
21 Lawyers who have appeared in front of me in Delaware Patent  
22 cases. And my view on Experts is that it's the Court's  
23 schedule and the Lawyers' schedule that really controls.

24 And Expert who sign on to be in the case do so  
25 understanding that their schedule -- they're going to have to

1 make their schedule as best as possible confirm with the  
2 Court's and the Lawyers' schedule.

3 But, we can work all that out later. But thanks for  
4 pointing that out. What else do you want to talk about?

5 MR. BERL: That's all, Your Honor.

6 THE COURT: Okay. Moderna, anything you want to  
7 chime in for me?

8 MS. CARSON: Your Honor, it's just that your  
9 inclination to perhaps hold off on setting a trial date, we  
10 agree with that. This is a very complex case, high stakes, and  
11 we do need time to go through discovery.

12 And the Parties are now engaged in a series of  
13 meet-and-confers. And I think that it's going to work itself  
14 out, just like we were able to work out a couple of the  
15 disputes that we were going to bring to Your Honor today, as  
16 things progressed.

17 But realistically we just think that the schedule  
18 that Plaintiffs are proposing is just way too compressed with  
19 substantial completion of documents in July of 2023, when we  
20 don't even have an Electronic Discovery Order in place yet.

21 THE COURT: Okay. Yeah, I took note of the -- the  
22 main difference was, Ms. Carson, the time period in the  
23 schedule. So I'll take note of your point again, Ms. Carson,  
24 and give that due consideration.

25 I think the other thing to supplement, I'll add into

1 the schedule -- and it may already be in there -- is the  
2 reminder on the meet-and-confer regarding discovery requests.  
3 Just to make it easier, you can just file letters, which we  
4 will docket everything, of course.

5 But meet-and-confer, you have a discovery dispute.  
6 You can't resolve it. At least you whittle it down, you do  
7 your best in good faith. And then, the one Party to the other,  
8 you can just file letters if you want.

9 I don't want to give you page limits. We will start  
10 with that. But just try to keep them under five pages, if  
11 possible. And then, I'll take a Response. And then, I can  
12 just get you on the phone and we can resolve it that way.

13 If it's more complex and we need to go in a  
14 courtroom, we will. But I'll put that process in the  
15 Scheduling Order, just make it a little easier for everybody.

16 So meet-and-confer and then letters on discovery  
17 disputes. And you can still file Motions if you want, if it's  
18 more complex.

19 Let's say -- I don't know -- a privilege issue or  
20 something that may require a log or in-camera review, but let's  
21 just take it as it comes. Okay?

22 All right. Well, unless there's something else, I  
23 will take a look at everyone's views. I'll issue the  
24 Scheduling Order, and then we will go from there.

25 MR. BERL: Thank you very much, Your Honor.

1                   THE COURT: Okay. Ms. Carson, anything else from  
2 you?

3                   MS. CARSON: No, Your Honor. Thank you for your -

4                   THE COURT: Okay.

5                   MS. CARSON: - time.

6                   THE COURT: Thank you, everyone, for your time.

7 Take care.

8                   MR. BERL: Okay.

9                   MS. CARSON: Okay.

10 (Proceedings concluded at 10:25 a.m.)

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C E R T I F I C A T I O N

I, VICTORIA O'CONNOR, court-approved transcriber, certify that the foregoing is a correct transcript from the official electronic sound recording of the proceedings in the above-entitled matter.



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Victoria O'Connor, CET

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March 20, 2023

Date

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